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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,058

02/18/2004

John Pafford

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07/12/2007

KRIEG DEVAULT LLP

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/781,058

**Applicant(s)**

PAFFORD ET AL.

**Examiner**

DAVID J. ISABELLA

**Art Unit**

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,73-75 and 77-116 is/are pending in the application.
- 4a) Of the above claim(s) 110-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,73-75 and 77-82,85-109 is/are rejected.
- 7) ☐ Claim(s) 83 and 84 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Status of the claims***

Claims 110-116 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 1,4-72 and 76 have been cancelled. Claims 2,3,73-75,77-109 are pending for action.

***Response to Applicant's Arguments***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Applicant's arguments filed 12/4/2006 have been fully considered and are persuasive.

Applicant has established a continuous priority chain, for portions of the claimed subject matter, back to application SN 08/740031. Accordingly, the outstanding rejection is vacated. The claimed recitations of "substantially pure osteogenic factor" and "impregnated" are not supported in earliest filed parent application. The first disclosure of these recitations appears in SN 08/740031 filed on 10/23/1996. For one example of each disclosure, see column 7, lines 20+ and column 13, lines 25+.

In one specific embodiment depicted in FIG. 1, the load bearing member of the spacer 10 is a bone dowel 11 soaked with an effective amount of an osteogenic composition to stimulate osteoinduction. Preferably, the osteogenic composition includes a substantially pure osteogenic factor in a pharmaceutically acceptable carrier. The dowel 10 includes

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An osteogenic material can be applied to the spacers of this invention by packing the chamber 25,130 with an osteogenic material 30,148 as shown in FIGS. 32 and 47, by impregnating the graft with a solution including an osteogenic composition or by both methods combined. The composition may be applied by the surgeon during surgery or the spacer may be supplied with the composition preapplied. In such cases, the osteogenic composition may be stabilized for transport and storage such as by freeze-drying.

Accordingly, applicant does not receive the earliest filing date of the first parent application but rather the earliest date for the claimed "substantially pure osteogenic factor" and "impregnated" is 10/23/1996.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,3,73-75,77-82,85-92-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vich (4877020) or Unicortical Dowels (University of Florida, as disclosed in applicant's specification) in view of Tucker et al [5674292] in view of Heggeness, et al (5514180).

Vich discloses a spinal spacer for insertion into a disc space between adjacent vertebrae comprising a cylindrical dowel configured for engagement with a concave

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space in the adjacent vertebrae. Vich fails to disclose the combination of osteogenic composition being impregnated with substantially pure osteogenic factor.

Tucker et al teaches impregnating porous bone with osteogenic factor, including bone morphogenic proteins.

Applicant's specification page 27 indicates that the osteogenic factors may be prepared by one skilled in the art and goes on to disclose various sources that serve to isolate the factors. Applicant's own specification fails to provide further disclosure regarding to the claimed feature of "substantially pure osteogenic factor". Applicant's specification fails to further elaborate on what constitutes "substantially pure".

Additionally, applicant's specification is devoid of any further processing of the factor, beyond what applicant disclosed to be prior art. Accordingly, since applicant's must rely on the disclosure of others in the field to support and/or give meaning to the "metes and bounds" of the recitation of "substantially pure", the admitted prior art suffices in meeting applicant's claimed limitation.

Where BMPs are included in the osteoinductive material, the BMPs may be naturally obtained or genetically engineered BMPs. Most preferably, the bone morphogenic protein is a BMP-2, such as recombinant human BMP-2. However, any bone morphogenic protein is contemplated including but not limited to bone morphogenetic proteins designated as BMP-1 through BMP-13. Such BMPs are available from Genetics Institute, Inc., 87 Cambridge Park Drive, Cambridge, Mass. 02140, and may also be prepared by one skilled in the art as described in U.S. Pat. No. 5,187,076 to Wozney et al.; U.S. Pat. No. 5,318,898 to Israel; U.S. Pat. No. 5,166,058 to Wang et al.; U.S. Pat. No. 5,356,875 to Wozney et al.; U.S. Pat. No. 4,877,864 to Wang et al.; U.S. Pat. No. 5,108,922 to Wang et al.; U.S. Pat. No. 5,116,738 to Wang et al.; U.S. Pat. No. 5,013,649 to Wang et al.; U.S. Pat. No. 5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al which are hereby incorporated by reference.

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Claims 2 and 3, see applicant's specification, page 27 and Heggeness, et al.

(See column 10, lines 49+).

The present invention is also directed to intervertebral devices comprising at least one osteoinductive material. Suitable osteoinductive materials include, but are not limited to, bone extracts and bone growth factors. Examples of bone growth factors include insulin-like bone growth factors (e.g. IGF-I and IGF-II), transforming growth factor  $\beta$  (e.g. TGF $\beta_1$  and TGF $\beta_2$ ), basic fibroblast growth factor (Basic FGF), acidic fibroblast growth factor (acidic FGF), platelet derived growth factor (PDGF), and bone morphogenetic proteins (e.g. BMP-1, BMP-2, BMP-3, BMP-4, BMP-5, BMP-6, and BMP-7). Other terms synonymous with bone growth factors include Somatomedin C, Skeletal Growth Factor, Cartilage Reducing Factor A, Cartilage Reducing Factor B, BMP-2a, BMP-2b, osteogenin, and osteogenic protein-1.

Claim 74, see threads on the dowel of Vich.

Claim 75, see method of impacting dowel of Vich into the intervertebral space.

Claims 77-79, see column 10, lines 49+ of Heggeness, et al.

Claims 80 and 81, see Unicortical Dowels (University of Florida, as disclosed in applicant's specification).

Claim 82, see column 10-11 of Heggeness, et al. Note, the claimed combination of the first and second osteogenic material does not preclude that both materials be present in the same matrix and packed in the chamber. With respect to claim 93, see figure 26 of Heggeness, et al.

Claims 85-89, see figure 1 of Vich.

Claims 90 and 93, see carrier as taught by Tucker et al [5674292].

Claims 91 and 92, see column 8, lines 55+ of Brekke.

Claim 94 is similar to claim 73 except it does not require the dowel to be cylindrical nor does it require the spacer be impregnated with the osteogenic factor. The Unicortical dowels (University of Florida) is a spacer having a chamber and sized for spacing adjacent vertebrae.

Claim 95, see Unicortical dowels.

Dependent claims 96-106 generally corresponds to the dependent claims 2,3,74-93 supra and are similarly rejected accordingly.

Claims 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vich (4877020) or Unicortical Dowels (University of Florida, as disclosed in applicant's specification) in view of Tucker et al [5674292] or Heggeness, et al (5514180) and further in view of Bianchi, et al (6033438). The specifics of threads design is taught by Bianchi, et al and if not inherent in Vich, to design the threads of Vich within the parameters as taught by Bianchi, et al would have been obvious to one with ordinary skill in the art since both references are attempting to solve the same problem, ie. spinal fusion.

***Allowable Subject Matter***

Claims 83 and 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
6/17/2007